510(k) summary

K100573

(in accordance to 21 C.F.R. § 807.92)

JUN - 7 2010

Submitter Identification

Holder / Headquarters:	MiE GmbH Hauptstrasse 112 23845 Seth, Schleswig-Holstein Germany
Telephone Number:	+49 4194 9977 0
Fax Number:	+49 4194 9977 55
Contact Person:	Thomas Kuehl th.kuehl@miegermany.de

Date summary prepared:	03/23/2010

Product Identifaction

Name:	SCINTRON
Common Name:	Gamma Camera Workstation for Acquisition, Reviewing and Processing
Classification Name:	Emission computed tomography system 21 C.F.R. § 892.1200
Classification:	Class II

Identification of Legally Market and Equivalent Devices

510(k) #	Device	Manufacturer
K953193	SCINTRON IV	MiE GmbH / MiE America Inc.
K023190	E.CAM Computer / e.soft Workstation	Siemens Medical Solutions ISA, Inc.
K914350	ICON COMPUTER SYSTEM	Siemens Gammasonics, Inc.
K080575	Corridor4DM	INVIA, LCC

Device Description

The SCINTRON is the modification and development of the SCINTRON IV. It is designed with Graphical User Interfaces for data acquisition, reviewing and processing of analog and digital Siemens gamma cameras. It controls static, dynamic, SPECT and whole body acquisitions. The SCINTRON uses industry standard and well tried PowerPC CPU on VMEbus which ensures long term support. Additionally to the clinical and networking programs, a variety of basic functions are available.

Intended Use

The Intended Use is similar and unchanged to the SCINTRON IV. The SCINTRON system is designed for data acquisition, reviewing and processing of analog and digital gamma cameras. It is intended to detect the location and distribution of gamma ray radionnuclides in the body or organ.
Following types of acquisition are provided:

- planar
- dynamic
- whole body
- SPECT (non positron emitting tomography)

Device Comparsion

Most vendors of gamma camera workstations provide an extensive acquiring and processing software packet as the SCINTRON has. The acquiring and processing software and hardware, which is designed of years by experiences and customer wishes, uses similar techniques to those of the predicate devices like the modified device SCINTRON IV.

Conclusion

The SCINTRON has similar intended use, operating principle and fundamental technologies as legally market devices. The design and development processes of the SCINTRON are conform to currently valid standards including applicable medical device safety and performance. All modifications do not significantly affect the safety and effectiveness of the device. All test results are, in opinion of MiE GmbH, that the SCINTRON is substantially equivalent to the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MiE GmbH
% Mr. Norman Von Hollen
Regulatory Manager
MiE America, Inc.
420 Bennett Road
ELK GROVE VILLAGE IL 60007

JUN - 7 2010

Re: K101013
Trade/Device Name: Scintron
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: May 24, 2010
Received: May 24, 2010

Dear Mr. Von Hollen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101013

Device Name: SCINTRON

Indications for Use:

The SCINTRON workstation for diagnostic nuclear medicine is designed for acquiring, processing and reviewing data from all type of MiE and Siemens digital and analog gamma cameras. The SCINTRON is used to perform static, dynamic and gated studies, as well as SPECT (non positron emitting tomography), whole body or planar procedure, on standing, seated or recumbent patients.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101013